PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Martin T. Gerber; John M. Swoyer	Confirmation No.	1410
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Docket No.:	1023-277US01		
Title:	IMPLANTABLE STIMULATION LEAD WITH FIXATION MECHANISM		

CERTIFICATE UNDER 37 CFR 1.8 I hereby certify that this correspondence is being transmitted via the United States Patent and Trademark Office electronic filing system on December 19, 2008.

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APPEAL BRIEF

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P.O. Box 1450,
Alexandria, VA 22313-1450

Sir:

This is an Appeal Brief in support of an appeal from the final Office Action mailed June 23, 2008, which finally rejected claims 1–5, 7–26, and 28–63. The Notice of Appeal was filed September 23, 2008 with a Pre-Appeal Brief Request for Review. A Notice of Panel Decision from the Pre-Appeal Brief Review was mailed on November 21, 2008. The period for filing this Brief runs through December 21, 2008.

On October 5, 2007, Appellant submitted a first Appeal Brief and paid the Appeal Brief fee. Prosecution was reopened following the filing of the first Appeal Brief. Accordingly, the previously-paid Appeal Brief fee may be applied to the present Appeal Brief. Please charge Deposit Account No. 50-1778 the amount of $30.00 for submission of this Appeal Brief, which reflects the difference between the previously-paid Appeal Brief fee and the increased Appeal Brief Fee. Please charge any additional fees that may be required or credit any overpayment to Deposit Account No. 50-1778.

TABLE OF CONTENTS

REAL PARTY OF INTEREST

The Real Party of Interest is Medtronic, Inc., of Minneapolis, Minnesota.

RELATED APPEALS AND INTERFERENCES

There are no related appeals or interferences.

STATUS OF CLAIMS

Claims 1–5, 7–26, and 28–63 are pending and are the subject of this Appeal. Claims 6 and 27 were canceled in the Amendment filed in response to the Office Action mailed December 28, 2007. Claims 64–67 are currently withdrawn as being drawn to a non-elected invention. The pending claims 1–6, 7–26, and 28–63 are set forth in the Claims Appendix.

Claims 1, 3, 8, 9, 11–15, 20, 21, 22, 24, 29, 32–36, 41, 42, 53, 55, 58, 59, 60, and 62 stand rejected under 35 U.S.C. § 102(e) as being unpatentable over U.S. Patent No. 7,255,695 to Falwell et al. (hereinafter "Falwell").

Claims 2, 4, 5, 7, 10, 23, 25, 26, 28, 30, 31, 43–47, 52, 54, 56, 57, 61, and 63 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Falwell.

STATUS OF AMENDMENTS

Appellant has not submitted any amendments subsequent to the issuance of the final Office Action mailed June 23, 2008. The pending claims are those presented in the Amendment filed on March 27, 2008.

SUMMARY OF CLAIMED SUBJECT MATTER

In general, the invention relates to implantable neurostimulation leads and methods for implanting the neurostimulation leads, where the leads include a fixation mechanism that helps prevent lead migration.[1] The fixation mechanism provides a less invasive technique for fixating the leads as compared to sutures or other surgical procedures.

[1] *See, e.g.*, Appellant's originally-filed disclosure at p. 3, ll. 20–23.

Independent claim 1 is directed to a neurostimulation lead[2] comprising a lead body[3] having a proximal end and a distal end, a plurality of stimulation electrodes[4] disposed adjacent the distal end of the lead body, and a fixation mechanism[5] mounted to the lead body at a position between one of the electrodes and the proximal end of the lead body, where the position is axially displaced from the plurality of stimulation electrodes[6]. The fixation mechanism includes one or more wire-like elements[7] that are expandable to fix the lead body at a tissue target site. As shown in FIG. 4A (reproduced below) and recited in claim 1, the fixation mechanism 43 is axially displaced from the plurality of stimulation electrodes 24 and between one of the electrodes 24 and the proximal end of the lead body 41. This arrangement of the fixation mechanism 43 may enable the fixation mechanism 43 to substantially fix the electrodes in place relative to a target stimulation site.[8]

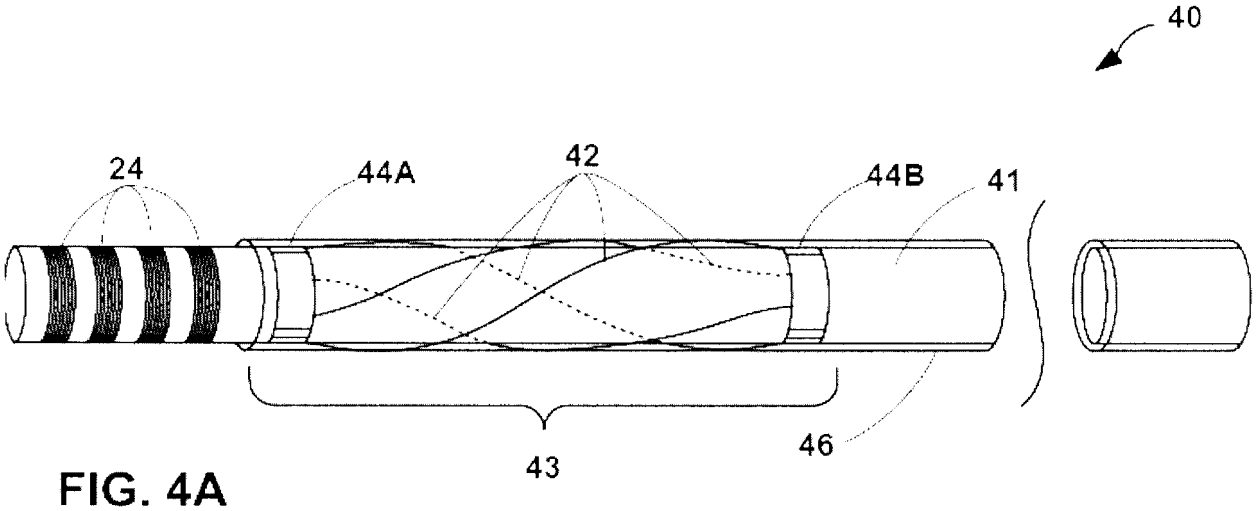

FIG. 4A

Independent claim 22 is directed to a neurostimulation system comprising an implantable neurostimulation pulse generator[9], a lead body[10] having a proximal end and a distal end, a

[2] *See, e.g., id.* at p. 9, ll. 10–11, p. 11, ll. 3–7, and lead 10 in FIG. 3 and lead 40 in FIG. 4A.
[3] *See, e.g., id.* at p. 8, l. 13 and lead body 41 in FIG. 4A.
[4] *See, e.g., id.* at p. 7, ll. 27–28, p. 9, ll. 12–13, p. 11, ll. 5–6, and electrodes 24 in FIGS. 3–6C.
[5] *See, e.g., id.* at p. 10, ll. 18–19, fixation mechanism 34 in FIG. 3, fixation mechanism 43 in FIGS. 4A–4B, fixation mechanism 43' in FIGS. 5A–5B, and fixation mechanism 63 in FIGS. 6A–6C.
[6] *See, e.g., id.* at FIGS. 4A–6C and the Amendment to the Specification in the Amendment dated January 18, 2007.
[7] *See, e.g.*, Appellant's originally-filed disclosure at p. 11, ll. 6–7, and wire-like elements 42 in FIGS. 4A–4B, wire-like elements 52 in FIGS. 5A–5B, and wire-like elements 62 in FIGS. 6A–6C.
[8] *See, e.g., id.* at p. 10, ll. 20–22.
[9] *See, e.g., id.* at p. 7, ll. 23 and p. 9, ll. 16–19.
[10] *See, e.g.*, Appellant's disclosure at FIG. 3 and p. 8, l. 13.

plurality of stimulation electrodes[11] disposed adjacent the distal end of the lead body, an electrical conductor[12] to electrically couple the implantable neurostimulation energy generator to a number of the electrodes[13], and a fixation mechanism[14] mounted to the lead body at a position between one of the electrodes and the proximal end of the lead body, where the position is axially displaced from the plurality of stimulation electrodes[15]. The fixation mechanism includes one or more wire-like elements[16] that are expandable to fix the lead body at a tissue target site.

Independent claim 42 is directed to a method comprising inserting a lead introducer[17] into a patient and inserting a lead into the patient via the introducer[18]. The lead includes a lead body[19] having a proximal end and a distal end, a plurality of stimulation electrodes[20] disposed on the lead body, and a fixation mechanism[21] mounted to the lead body at a position between one of the electrodes and the proximal end of the lead body, the position being axially displaced from the plurality of stimulation electrodes[22]. The fixation mechanism includes one or more wire-like elements[23] that are expandable to fix the lead body at a tissue target site. In accordance with claim 42, the method further includes removing a restraint mechanism on the fixation mechanism[24], thereby permitting the wire-like elements to expand.

Independent claim 53 is directed to a stimulation lead comprising a lead body[25] having a proximal end and a distal end, a plurality of stimulation electrodes[26] disposed on the lead body,

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[11] *See, e.g., id.* at p. 7, ll. 27–28, p. 9, ll. 12–13, p. 11, ll. 5–6, and electrodes 24 in FIGS. 3–6C.
[12] *See, e.g., id.* at p. 8, ll. 3–5 and p. 12, ll. 15–17.
[13] *See, e.g., id.* at p. 8, ll. 3–5 and p. 9, ll. 15–16.
[14] *See, e.g., id.* at p. 10, ll. 18–19, fixation mechanism 34 in FIG. 3, fixation mechanism 43 in FIGS. 4A–4B, fixation mechanism 43' in FIGS. 5A–5B, and fixation mechanism 63 in FIGS. 6A–6C.
[15] *See, e.g., id.* at FIGS. 4A–6C and the Amendment to the Specification in the Amendment dated January 18, 2007.
[16] *See, e.g.*, Appellant's originally-filed disclosure at p. 11, ll. 6–7, and wire-like elements 42 in FIGS. 4A–4B, wire-like elements 52 in FIGS. 5A–5B, and wire-like elements 62 in FIGS. 6A–6C.
[17] *See, e.g., id.* at p. 12, ll. , 22–24, p. 16, ll. 25–27 and lead introducer 46 in FIG. 4A and 4B.
[18] *See, e.g., id.* at FIG. 7 and p. 17, ll. 3–5.
[19] *See, e.g., id.* at FIG. 3 and p. 8, l. 13.
[20] *See, e.g., id.* at p. 7, ll. 27–28, p. 9, ll. 12–13, p. 11, ll. 5–6, and electrodes 24 in FIGS. 3–6C.
[21] *See, e.g., id.* at p. 10, ll. 18–19, fixation mechanism 34 in FIG. 3, fixation mechanism 43 in FIGS. 4A–4B, fixation mechanism 43' in FIGS. 5A–5B, and fixation mechanism 63 in FIGS. 6A–6C.
[22] *See, e.g., id.* at FIGS. 4A–6C and the Amendment to the Specification in the Amendment dated January 18, 2007.
[23] *See, e.g.*, Appellant's originally-filed disclosure at p. 11, ll. 6–7, and wire-like elements 42 in FIGS. 4A–4B, wire-like elements 52 in FIGS. 5A–5B, and wire-like elements 62 in FIGS. 6A–6C.
[24] *See, e.g., id.* at FIG. 7 and p. 17, ll. 20–22.
[25] *See, e.g., id.* at FIG. 3 and p. 8, l. 13.
[26] *See, e.g., id.* at p. 7, ll. 27–28, p. 9, ll. 12–13, p. 11, ll. 5–6, and electrodes 24 in FIGS. 3–6C.

and means for fixing[27] the lead body relative to tissue proximate a tissue target site. The fixing means[28] includes wire-like elements[29] that are expandable to fix the lead body at a tissue target site. The fixing means is mounted to the lead body at a position between one of the electrodes and the proximal end of the lead body, and the position is axially displaced from the plurality of stimulation electrodes[30].

Dependent claim 58 depends from independent claim 53 and recites a means for restraining the wire-like elements again expansion[31], where the wire-like elements expand upon removal of at least part of the restraining means.

Dependent claims 3, 24, and 55 depend from independent claims 1, 22, and 53, respectively, and each recite a fixation mechanism that includes wire-like elements each having a proximal joint[32] where a proximal end of the respective wire-like element meets the lead body and a distal joint[33] where a distal end of the respective wire-like element meets the lead body, and where the distal joint is weaker than the proximal joint.[34] After a lead has been implanted within a patient for an amount of time, fibrous ingrowth may develop around the lead.[35] The weaker distal joint provides a feature that helps facilitate explantation of a lead, for example, by reducing resistance attributable to the fibrous ingrowth.[36] For example, during explantation of the lead, the weaker distal joint may break under sufficient force, thereby allowing the wire-like elements of the fixation mechanism to be withdrawn around the fibrous ingrowth.[37]

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[27] *See, e.g., id.* at p. 10, ll. 18–19, p. 7, ll. 8–10, p. 10, l. 22 to p. 11, ll. 2, p. 11, ll. 7–14, p. 13, l. 26 to p. 14, l. 2, p. 14, ll. 19–24, fixation mechanism 34 in FIG. 3, fixation mechanism 43 in FIGS. 4A–4B, fixation mechanism 43' in FIGS. 5A–5B, and fixation mechanism 63 in FIGS. 6A–6C.

[28] *See, e.g., id.* at p. 10, ll. 18–19, p. 7, ll. 8–10, p. 10, l. 22 to p. 11, ll. 2, p. 11, ll. 7–14, p. 13, l. 26 to p. 14, l. 2, p. 14, ll. 19–24, fixation mechanism 34 in FIG. 3, fixation mechanism 43 in FIGS. 4A–4B, fixation mechanism 43' in FIGS. 5A–5B, and fixation mechanism 63 in FIGS. 6A–6C.

[29] *See, e.g., id.* at p. 11, ll. 6–7, and wire-like elements 42 in FIGS. 4A–4B, wire-like elements 52 in FIGS. 5A–5B, and wire-like elements 62 in FIGS. 6A–6C.

[30] *See, e.g., id.* at FIGS. 4A–6C and the Amendment to the Specification in the Amendment dated January 18, 2007.

[31] *See, e.g., id.* at p. 4, ll. 6–13, p. 12, ll. 20–26, and p. 14, ll. 25–26, introducer 46 in FIGS. 4A and 4B, and stylet 66 in FIGS. 6A and 6B.

[32] *See, e.g., id.* at FIG. 6C and p. 16, ll. 4–6.

[33] *See, e.g., id.*

[34] *See, e.g., id.* at p. 16, ll. 6–12.

[35] *See, e.g., id.* at p. 15, l. 28 – p. 16, l. 2 and FIGS. 6B–6C (fibrous ingrown 69).

[36] *See, e.g., id.*

[37] *See, e.g., id.* at FIG. 6C.

GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Appellant submits the following grounds of rejection to be reviewed on appeal:

(1) The first ground of rejection to be reviewed on appeal is the rejection of claims 1, 3, 8, 9, 11–15, 20, 21, 22, 24, 29, 32–36, 41, 42, 53, 55, 58, 59, 60, and 62 under 35 U.S.C. § 102(e) as being unpatentable over Falwell.

(2) The second ground of rejection to be reviewed on appeal is the rejection of claims 2, 4, 5, 7, 10, 23, 25, 26, 28, 30, 31, 43–47, 52, 54, 56, 57, 61, and 63 under 35 U.S.C. § 103(a) as being unpatentable over Falwell.

ARGUMENT

Appellant respectfully traverses the current rejection of claims 1–6, 7–26, and 28–63 presented in the final Office Action dated June 23, 2008, and requests reversal by the Board of Patent Appeals based on the arguments below. For each ground of rejection, Appellant respectfully requests separate review of each set of claims argued under separate headings. For at least the reasons presented below, the Examiner has failed to establish a *prima facie* case of anticipation or obviousness with respect to Appellant's claims 1–6, 7–26, and 28–63.

FIRST GROUND OF REJECTION UNDER APPEAL

Claims 1, 3, 8, 9, 11–15, 20, 21, 22, 24, 29, 32–36, 41, 42, 53, 55, 58, 59, 60, and 62 stand rejected under 35 U.S.C. § 102(e) as being unpatentable over Falwell. Appellant respectfully submits that the rejection of claims 1, 3, 8, 9, 11–15, 20, 21, 22, 24, 29, 32–36, 41, 42, 53, 55, 58, 59, 60, and 62 is in error and should be reversed. In order to support an anticipation rejection under 35 U.S.C. § 102(e), it is well established that a prior art reference must disclose each and every element of a claim.[38] If a prior art reference fails to disclose any element of a claim, then rejection under 35 U.S.C. § 102(e) is improper. [39] Falwell fails to

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[38] *See Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 231 USPQ 81 (Fed. Cir. 1986) ("it is axiomatic that for prior art to anticipate under 102 it has to meet every element of the claimed invention").

[39] *Id.*; *see also Lewmar Marine, Inc. v. Barient, Inc.* 827 F.2d 744, 3 USPQ.2d 1766 (Fed. Cir. 1987); *In re Bond*, 910 F.2d 831, 15 USPQ.2d 1566 (CAFC 1990); *C.R. Bard, Inc. v. MP Systems, Inc.*, 157 F.3d 1340, 48 USPQ.2d 1225 (Fed. Cir. 1998); *Oney v. Ratliff*, 182 F.3d 893, 51 USPQ.2d 1697 (Fed. Cir. 1999); *Apple Computer, Inc. v. Articulate Systems, Inc.*, 234 F.3d 14, 57 USPQ.2d 1057 (Fed. Cir. 2000).

disclose each and every element of Appellant's claims, and accordingly, the Examiner's rejection of Appellant's independent claims is improper and should be reversed.

INDEPENDENT CLAIMS 1, 22, AND 53

Independent claim 1 recites a neurostimulation lead comprising a lead body, a plurality of stimulation electrodes, and a fixation mechanism including one or more wire-like elements that are expandable to fix a lead body at a target tissue site. According to claim 1, the fixation mechanism is mounted between one of the electrodes and a proximal end of the lead body, and is axially displaced from the plurality of stimulation electrodes. Thus, claim 1 requires the lead to include a plurality of stimulation electrodes in addition to the fixation mechanism.

In support of the rejection of Appellant's independent claim 1, the Examiner cited FIG. 14 of Falwell and characterized the braided conductive members 28B and 28C as "a plurality of stimulation electrodes" and the braided conductive member 28A as a fixation mechanism.[40] Falwell discloses that the conductive members 28A–2C are each made of a plurality of interlaced, electrically conductive filaments 34 that alone or in combination with other filaments may form isolated electrodes.[41] The Examiner appeared to rely on the fact that discrete sectors of each conductive member 28A–28C may be activated independently to support the conclusion that the conductive members 28B, 28C of Falwell may be considered electrodes and the conductive member 28A may be considered an expandable fixation mechanism that is axially displaced from the electrodes.[42] Appellant respectfully disagrees with the Examiner's interpretation of Falwell.

The Examiner's interpretation of Falwell overlooks the fact that each conductive member 28A–28C disclosed by Falwell defines one or more electrodes.[43] Regardless of whether the electrodes defined by the conductive members 28A–28C may be activated independently or concurrently, the conductive members 28A–28C are each conductive members that defines one or more electrodes.[44] Thus, if the Examiner is characterizing the conductive members 28B and 28C as stimulation electrodes, the conductive member 28A would also reasonably be considered

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[40] Final Office Action dated June 23, 2008 at p. 3.
[41] Falwell at col. 5, ll. 60–62 and col. 6, ll. 16–21.
[42] Final Office Action dated June 23, 2008 at p. 3, citing col. 11, ll. 63–63 of Falwell.
[43] Falwell at col. 6, ll. 16–17.
[44] Falwell at col. 6, ll. 16–17.

a stimulation electrode. In this way, all of the conductive members 28A–28C shown in FIG. 14 of Falwell define a plurality of electrodes, rather than a plurality of electrodes and a fixation mechanism. In contrast, Appellant's claim 1 recites a lead that includes a plurality of stimulation electrodes in addition to a fixation mechanism that is axially displaced from the plurality of stimulation electrodes.

Each and every claim term must be given meaning, and the claimed invention as a whole must be considered.[45] Appellant's claim 1 clearly requires a fixation mechanism that is axially displaced from, i.e., separate from, a plurality of stimulation electrodes. Falwell does not disclose a lead that includes both a plurality of stimulation electrodes and a fixation mechanism, but rather, only discloses a plurality of conductive members that may be used to detect electrical activity during mapping procedures or to apply energy during an ablation procedure.[46] The conductive member 28A cannot reasonably be characterized as a fixation mechanism that is axially displaced from a plurality of electrodes of the Falwell catheter, as proposed by the Examiner, because the conductive member 28A defines at least one of the electrodes.

Falwell also indicates that the conductive member 28A does not fix the catheter 10 at a tissue site, and, therefore, cannot be a fixation mechanism of a lead. For example, with respect to FIG. 22, which illustrates a catheter shaft 12 placed in an ostium of a pulmonary vein 154, Falwell states that the conductive member 28 may be expanded to its deployed position and the catheter shaft 12 may be subsequently advanced into the pulmonary vein 154.[47] This indicates that the conductive member 28 does not fix the catheter 12 to tissue. Falwell also discloses that a lubricious coating may be applied to a conductive member 28 to reduce the possibility of vascular or atrial damage.[48] Moreover, Falwell discloses that a shroud may cover at least a portion of an expanded conductive member 28, where the shroud does "not reduce the mobility of braided conductive member 28."[49] Accordingly, it appears that the conductive member 28 is intended to be mobile when expanded within tissue. In contrast, Appellant's claim 1 specifically requires the fixation mechanism to include one or more wire-like elements that are expandable to fix a lead body at a tissue target site.

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[45] MPEP § 2141.02.
[46] Falwell at col. 8, ll. 1–3.
[47] Falwell at col. 19, ll. 2–10.
[48] Falwell at col. 14, l. 64 – col. 15, l. 4.
[49] Falwell at col. 16, ll. 46–63; *see* FIGS. 20A–20C.

For at least these reasons, the Examiner failed to show that Falwell discloses a lead that includes a fixation mechanism including one or more wire-like elements, where the fixation mechanism is axially displaced from a plurality of stimulation electrodes and is mounted to the lead body at a position between one of the electrodes and the proximal end of the lead body. Accordingly, the Examiner's rejection of independent claim 1 as being anticipated by Falwell is improper.

For at least the reasons discussed above with respect to independent claim 1, Falwell fails to anticipate Appellant's independent claims 22 and 53. Independent claim 22 also requires a lead body, a plurality of stimulation electrodes, and a fixation mechanism including one or more wire-like elements that are expandable to fix the lead body at a target tissue site, where the fixation mechanism is mounted between one of the electrodes and a proximal end of the lead body and is axially displaced from the plurality of stimulation electrodes. Independent claim 53 requires a lead body, a plurality of stimulation electrodes, and means for fixing the lead body relative to tissue proximate a tissue target site, where the fixing means includes wire-like elements that are expandable to fix the lead body at the tissue target site. According to claim 53, the fixing means is mounted to the lead body at a position between one of the electrodes and the proximal end of the lead body, and the position is axially displaced from the plurality of stimulation electrodes.

INDEPENDENT CLAIM 42

Appellant's independent claim 42 recites a method that comprises inserting a lead introducer into a patient, inserting a lead into the patient via the introducer, wherein the lead includes, among other things, a fixation mechanism that is axially displaced from a plurality of stimulation electrodes, and removing a restraint mechanism on the fixation mechanism, thereby permitting wire-like elements of the fixation mechanism to expand. As discussed above with respect to independent claim 1, the Examiner failed to demonstrate that Falwell discloses or suggests a lead that includes a fixation mechanism that is axially displaced from a plurality of stimulation electrodes.

In addition, the method of independent claim 42 requires removing a restraint mechanism on the fixation mechanism, thereby permitting the wire-like elements to expand. Falwell fails to

disclose a restraint mechanism that permits the conductive member 28 to expand upon removal of the restraint mechanism. Instead, Falwell discloses that movement of a sheath 26 over an inner member 22 causes a conductive member 28 to expand radially.[50] Falwell also discloses that, "[a]s shaft 26 is moved distally, braided conductive member 28 emerges or everts from shaft 12."[51] While Falwell discloses these techniques for causing the conductive member 28 to radially expand, none of these techniques includes a restraint mechanism that is removed in order to expand the conductive member 28. Thus, Falwell cannot anticipate independent claim 42. Accordingly, the Examiner's rejection of independent claim 42 as being anticipated by Falwell is improper and should be reversed.

DEPENDENT CLAIMS 3, 24, AND 55

Claims 3, 24, and 55 specify that the wire-like elements of the fixation mechanisms or fixation means of claim 1, 22, and 53, respectively, each have a proximal joint where a proximal end of the respective wire-like element meets the lead body and a distal joint where a distal end of the respective wire-like element meets the lead body. Claims 3, 24, and 55 require the distal joint to be weaker than the proximal joint. An example of a wire-like element including a weaker distal joint is shown in FIGS. 6A-6C of Appellant's disclosure. FIGS. 6B and 6C are reproduced below.

[50] Falwell at col. 5, ll. 14–18.
[51] Falwell at col. 14, ll. 26–28.

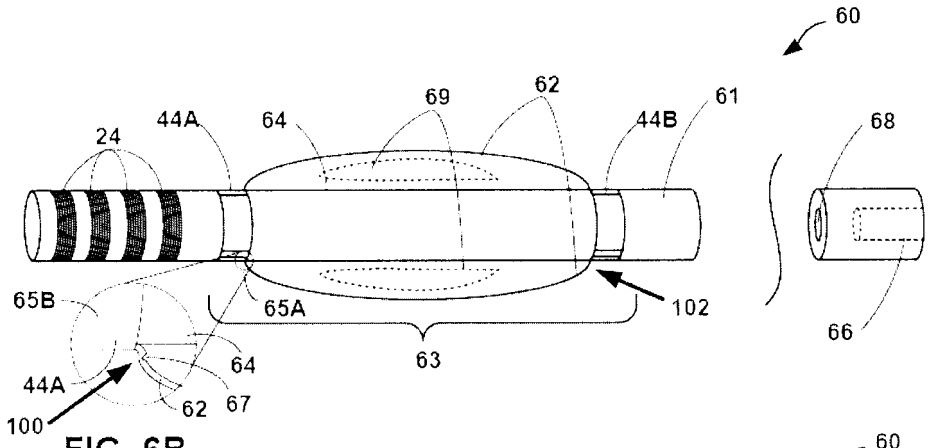

FIG. 6B

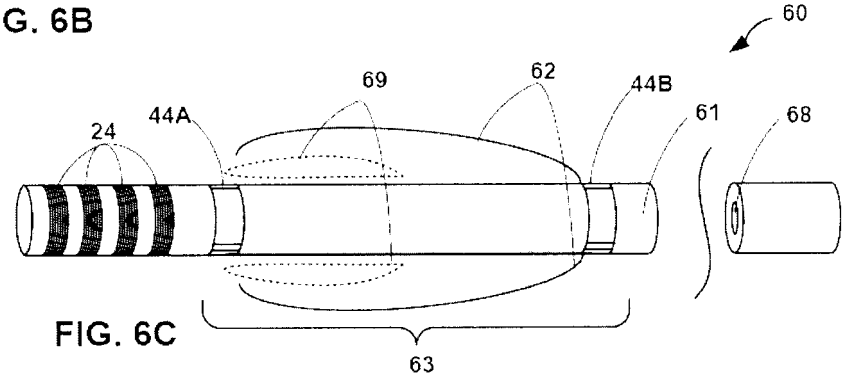

FIG. 6C

In the FIG. 6B, the wire-like elements 62 of the fixation mechanism 63 each include a distal joint (labeled by Appellant as "100" in FIG. 6B above) that is weaker than a proximal joint (labeled by Appellant "102" in FIG. 6B above). As provided in Appellant's originally-filed disclosure, a weaker distal joint provides a feature that helps facilitate explantation of a lead, for example, by reducing resistance attributable to the fibrous ingrowth.[52] By promoting breakage of the distal joint during explantation of the lead, the wire-like elements of the fixation mechanism may be withdrawn around the fibrous ingrowth.[53] Reducing resistance during lead withdrawal that is attributable to fibrous ingrowth may help minimize damage to tissue surrounding the lead during lead explantation, as well as minimize the amount of force necessary to withdraw the lead from a patient.

Despite rejecting claims 3, 24, and 55 under 35 U.S.C. § 102(e) as being anticipated by Falwell, the Examiner failed to provide any support for the conclusion that Falwell discloses each element of claims 3, 24, and 55. The Examiner failed to cite to any disclosure within

[52] *See, e.g.*, Appellant's originally-filed disclosure at paragraph [0070].
[53] *See, e.g.*, *id.* at FIG. 6C.

Falwell that demonstrates Falwell discloses wire-like elements having a proximal joint and a distal joint that is weaker than the proximal joint. As provided in 37 C.F.R. 1.104(c) (2), the Examiner must designate the particular part of a reference as nearly as practicable. However, with respect to claims 3, 24, and 55, as well as many of the other dependent claims, the Examiner has failed to do so. To the extent the final Office Action mailed on June 23, 2008 provides support for the assertion that Dahl discloses each and every element of claims 1, 3, 8, 9, 11–15, 20, 21, 22, 24, 29, 32–36, 41, 42, 53, 55, 58, 59, 60, and 62, the Office Action states:

> Fallwell [sic] et al [sic] disclose an embodiment in Fig. 14 that comprises a lead body having a proximal end 12 and a distal end 18. The examiner is interpreting 28B and 28C to comprise a plurality of stimulation electrodes and 28A to comprise a fixation mechanism. Col. 11, lines 63-63 teach the mapping and ablations [sic] sectors and/or wires may be activated independently, and may be activated concurrently.

The Examiner did not cite to disclosure within Falwell that demonstrates Falwell discloses wire-like elements having a proximal joint and a distal joint that is weaker than the proximal joint. Accordingly, the rejection of claims 3, 24, and 55 is improper and should be reversed.

Falwell fails to disclose or suggest wire-like elements having a proximal joint and a distal joint that is weaker than the proximal joint, as required by claims 3, 24, and 55. Falwell discloses that a proximal end of a conductive member 28 is anchored to the catheter shaft 12 using an anchor band 90, and the distal end is clamped to an activating shaft using another anchor band 92.[54] However, even if the conductive member 28A is a fixation mechanism, an assertion with which Appellant disagrees, Falwell does not discuss the joint strength of the filaments of the conductive member 28A, and lacks any disclosure that would have suggested the requirements of claims 3, 24, and 55.

Given the fact that Falwell clearly fails to provide any disclosure that discloses or even suggests the limitations of claims 3, 24, and 55, and the lack of support provided by the Examiner for the rejection of claims 3, 24, and 55, the rejection of claims 3, 24, and 55 is improper and should be reversed.

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[54] Falwell at col. 14, ll. 19–24 and FIGS. 16A–16C.

DEPENDENT CLAIMS 8 AND 29

Claims 8 and 29 recite a restraint mechanism to restrain the wire-like elements of a fixation mechanism against expansion, where the wire-like elements expand upon removal of at least part of the restraint mechanism. Falwell fails to disclose or suggest each and every limitation of claims 8 and 29.

As an initial matter, Appellant respectfully submits that the Examiner failed to meet the burden of demonstrating that Falwell discloses the elements of claims 8 and 29. For example, although the Examiner broadly asserted that Falwell anticipated claims 8 and 29, the Examiner failed to provide any support for the conclusion that Falwell discloses a restraint mechanism that restrains the wire-like elements of a fixation mechanism against expansion, where the wire-like elements expand upon removal of at least part of the restraint mechanism.

Falwell fails to provide any disclosure that discloses or even suggests the limitations of claims 8 and 29. As noted above, the Examiner characterized the braided conductive member 28A as a fixation mechanism.[55] Even if the conductive member 28A is a fixation mechanism including a wire-like element, an assertion with which Appellant disagrees, Falwell does not disclose or even suggest that the conductive member 28A expands upon removal of a restraint mechanism, as required by claims 8 and 29. Moreover, Falwell does not suggest that a restraint mechanism in any way restrains the conductive member 28A. Instead, Falwell discloses that the braided conductive member may be radially expanded by moving an inner member 22 relative to a sheath 26 or by sliding the sheath 26 over the inner member 22, as shown in FIGS. 4 and 5 of Falwell.[56]

For at least these reasons, the rejection of claims 8 and 29 is improper and should be reversed.

DEPENDENT CLAIMS 11, 32, AND 62

Claims 11 and 32 each recite a lead including a lead body, where at least a portion of the lead body is elastic, causing a diameter of the lead body to decrease when the lead body portion is stretched. Claim 62, which depends from claim 32, recites a stylet that provides an axial force that stretches the elastic portion of the lead body to restrain the wire-like elements against

[55] Final Office Action at p. 3.
[56] Falwell at col. 5, ll. 14–27.

expansion. While the Examiner rejected claims 11 and 32 as being anticipated by Falwell, the Examiner failed to address the specific limitations of claims 11 and 32. The Examiner provided absolutely no explanation of how Falwell discloses a lead body including an elastic portion or a stylet that provides an axial force that stretches the elastic portion.

Falwell fails to disclose or even suggest a lead body that is elastic, much less a lead body that may be stretched to decrease a diameter of the lead body, much less an inner stylet that provides an axial force to stretch a lead body. Accordingly, the rejection of claims 11, 32, and 62 is improper and should be reversed.

For at least these reasons, claims 1, 3, 8, 9, 11–15, 20, 21, 22, 24, 29, 32–36, 41, 42, 53, 55, 58, 59, 60, and 62 are patentable over Falwell, and the rejection of claims 1, 3, 8, 9, 11–15, 20, 21, 22, 24, 29, 32–36, 41, 42, 53, 55, 58, 59, 60, and 62 should be reversed.

SECOND GROUND OF REJECTION UNDER APPEAL

Claims 2, 4, 5, 7, 10, 23, 25, 26, 28, 30, 31, 43–47, 52, 54, 56, 57, 61, and 63 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Falwell. Claims 2, 4, 5, 7, 10, 23, 25, 26, 28, 30, 31, 43–47, 52, 54, 56, 57, 61, and 63 depend from one of independent claims 1, 22, 42, and 53. Thus, claims 2, 4, 5, 7, 10, 23, 25, 26, 28, 30, 31, 43–47, 52, 54, 56, 57, 61, and 63 are patentable over Falwell for at least the reasons discussed above with respect to independent claim 1. In addition, Falwell fails to disclose or suggest each and every element of Appellant's dependent claims.

DEPENDENT CLAIMS 10, 31, AND 43

Claims 10 and 31 depend from claims 8 and 29, respectively, and specify that the restraint mechanism includes a stylet that is accommodated by an inner lumen of the lead. Claim 43 recites a method that includes removing a restraint by withdrawing at least part of a stylet from a lumen of the lead, thereby releasing a fixation mechanism to expand. Falwell fails to disclose or suggest each and every limitation of claims 10, 31, and 43.

The Examiner failed to meet the burden of demonstrating that Falwell suggests the elements of claims 10, 31, and 43. In support of the rejection of claims 10, 31, and 43 as being obvious in view of Falwell, the Examiner stated that "one of ordinary skill in the art would have

found it obvious to construct the shaft portion 12 with a lumen to accommodate a stylet because a stylet is an art recognized actuating device and Falwell et al suggests a thumb wheel . . . may be connected to one or more pull wires which extend through shaft portion 12 and are connected to the distal end 18 of the catheter at an off-axis location."[57] However, claim 10 does not merely recite a stylet. Rather, in addition to reciting that a neurostimulation lead comprises an inner lumen that accommodates a stylet, claims 10 and 31 specify that the restraint mechanism that restrains the wire-like elements of a fixation mechanism against expansion comprises the stylet. Claim 43 recites a method comprising withdrawing at least part of a stylet from a lumen of the lead, thereby releasing the fixation mechanism. The Examiner appears to have disregarded these elements of claims 10, 31, and 43.

Falwell fails to disclose or even suggest the restraint mechanism recited by claims 10, 31, and 43. The thumb wheel disclosed by Falwell, which the Examiner apparently characterized as a restraint mechanism, is merely used to deflect the distal end of the Falwell catheter.[58] Falwell does not disclose or even suggest that actuation of the thumb wheel restrains the filaments 34 of the conductive members 28A–28C. Instead, Falwell states that movement of a sheath 26 over an inner member 22 causes a conductive member 28 to expand radially.[59] Thus, Falwell does not disclose or suggest a restraint mechanism that restrains wire-like elements against expansion, where the wire-like elements expand upon removal of at least part of the restraint mechanism, as required by claims 8 and 29, from which claims 10 and 31, respectively, depend. Accordingly, Falwell does not disclose or suggest a restraint mechanism that comprises a stylet, as recited by claims 10 and 31, or a method comprising withdrawing at least part of a stylet from a lumen of the lead, thereby releasing the fixation mechanism to expand, as recited by claim 43.

For at least these reasons, one having ordinary skill in the art would not have had any apparent reason to modify Falwell to construct the shaft portion 12 of the catheter to accommodate a lumen in order to restrain the wire-like elements of a fixation mechanism against expansion. Moreover, even if the shaft portion 12 of the Falwell catheter was modified to accommodate a stylet, as suggested by the Examiner, the resulting structure would not include each and every element of Appellant's claims 10 and 31. For example, Falwell fails to provide

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[57] Office Action at p. 4.
[58] Falwell at col. 4, ll. 61–63.
[59] *Id.* at col. 5, ll. 14–18.

any disclosure that suggests that a stylet within a lumen of the shaft potion 12 would restrain the conductive member 28A against expansion. Instead, a stylet within a lumen of the shaft portion 12 would appear to deflect the distal tip 18 of the Falwell catheter without having any affect on the conductive member 28A. In this sense, the stylet merely serves as a guidewire to steer the distal tip 18 of the catheter. Even if a stylet is an "art recognized actuating device" as proposed by the Examiner, an assertion with which Appellant does not necessarily agree, the Examiner has not offered any support for the conclusion that a restraint mechanism comprising a stylet that restrains the wire-like elements of a fixation mechanism against expansion is obvious in view of Falwell.

For at least these reasons, the rejection of claims 10, 31, and 43 is improper and should be reversed.

DEPENDENT CLAIM 45

Claim 45 specifies that the method of claim 42 further includes detaching a distal end of each wire-like element of a fixation mechanism of a lead, and withdrawing the lead from the target site. Falwell fails to disclose or suggest detaching a distal end of a wire-like element of the conductive member 28A, which the Examiner characterized as a fixation mechanism, and withdrawing the lead from the target site. The Examiner failed to point to any suggestion of such a feature in Falwell or provide any support for the rejection of claim 45. Moreover, there would not have been any apparent reason for a person having ordinary skill in the art to modify Falwell to include such features. As noted above, detaching a distal end of a wire-like element of a fixation mechanism may help facilitate explantation of a lead, for example, by reducing resistance attributable to the fibrous ingrowth around the fixation mechanism.[60] Falwell discloses that its catheter is used for mapping and ablation purposes, and fails to suggest that there may be a risk of its catheter being encumbered by fibrous tissue ingrowth. Falwell discloses that its catheter is configured to be moved around within the patient and fails to contemplate fibrous tissue ingrowth around its catheter.[61]

For at least these reasons, the rejection of claim 45 is improper and should be reversed.

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[60] *See, e.g.*, Appellant's originally-filed disclosure at paragraph [0070].
[61] Falwell at col. 19, ll. 39-41.

DEPENDENT CLAIM 63

Claim 63 specifies that a stylet provides an axial force that stretches an elastic portion of a lead body to restrain the wire-like elements of a fixation mechanism against expansion, and the elastic portion of the lead body decreases in length upon removal of the stylet. In support of the rejection of claim 63 as being obvious in view of Falwell, the Examiner asserted that "one of ordinary skill in the art would have found it obvious to construct the shaft portion 12 with a lumen to accommodate a stylet because a stylet is an art recognized actuating device and Falwell et al [sic] suggest a thumb wheel . . . may be connected to one or more pull wires which extend through shaft portion 12 and are connected to the distal end 18 of the catheter at an off-axis location."[62]

As noted above with respect to the rejection of claim 10, the thumb wheel disclosed by Falwell is not a restraint mechanism, but is merely used to steer the distal end of the Falwell catheter.[63] Falwell does not even suggest that actuation of the thumb wheel restrains the filaments 34 of the conductive members 28A (which the Examiner characterized as a wire-like element) or that the filaments 34 are restrained as the distal end 18 of the Falwell catheter deflects. Instead, Falwell discloses that the distal end of the catheter is deflected to steer the catheter.[64]

Moreover, Appellant's claim 63 requires a lead body that includes an elastic portion. Falwell fails to disclose or suggest that its catheter includes an elastic portion that decreases in length upon removal of a stylet from a lumen of the lead. Indeed, Falwell does not contemplate a catheter that may change length. The Examiner has failed to specifically address this limitation of claim 63. For at least these reasons, the rejection of claim 63 is improper and should be reversed.

For at least these reasons, claims 2, 4, 5, 7, 10, 23, 25, 26, 28, 30, 31, 43–47, 52, 54, 56, 57, 61, and 63 are patentable over Falwell, and the rejection of claims 2, 4, 5, 7, 10, 23, 25, 26, 28, 30, 31, 43–47, 52, 54, 56, 57, 61, and 63 should be reversed.

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[62] Office Action at p. 4.
[63] Falwell at col. 4, ll. 61–63.
[64] Falwell at col. 4, ll. 59–63.

CONCLUSION OF ARGUMENT

The Examiner has failed to meet the burden of establishing a *prima facie* case of non-patentability with respect to claims 1–5, 7–26, and 28–63. In view of Appellant's arguments, the final rejection of claims 1–5, 7–26, and 28–63 is improper and should be reversed, and all of the pending claims should be allowed. Appellant respectfully requests separate review by the Board for each of the grounds or rejections addressed above under separate headings.

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CLAIMS APPENDIX

Claim 1: A neurostimulation lead comprising:

a lead body having a proximal end and a distal end;

a plurality of stimulation electrodes disposed adjacent the distal end of the lead body; and

a fixation mechanism mounted to the lead body at a position between one of the electrodes and the proximal end of the lead body, the fixation mechanism including one or more wire-like elements that are expandable to fix the lead body at a tissue target site, wherein the position is axially displaced from the plurality of stimulation electrodes.

Claim 2: The neurostimulation lead of claim 1, wherein each of the wire-like elements includes an elastic material.

Claim 3: The neurostimulation lead of claim 1, each of the wire-like elements having a proximal joint where the proximal end of the wire-like element meets the lead body, and a distal joint where the distal end of the wire-like element meets the lead body, wherein the distal joint is weaker than the proximal joint.

Claim 4: The neurostimulation lead of claim 1, wherein each of the wire-like elements includes a shape memory alloy.

Claim 5: The neurostimulation lead of claim 1, wherein each of the wire-like elements includes a super-elastic material.

Claim 7: The neurostimulation lead of claim 1, further comprising an inner lumen to accommodate a stylet.

Claim 8: The neurostimulation lead of claim 1, further comprising a restraint mechanism to restrain the wire-like elements against expansion, wherein the wire-like elements expand upon removal of at least part of the restraint mechanism.

Claim 9: The neurostimulation lead of claim 8, wherein the restraint mechanism includes a lead introducer, the lead introducer defining a lead introducer lumen sized to accommodate the stimulation lead body.

Claim 10: The neurostimulation lead of claim 8, wherein the restraint mechanism includes a stylet, the stylet accommodated by an inner lumen of the neurostimulation lead.

Claim 11: The neurostimulation lead of claim 1, wherein at least a portion of the lead body is elastic, causing a diameter of the lead body portion to decrease when the lead body portion is stretched.

Claim 12: The neurostimulation lead of claim 1, wherein each of the wire-like elements is configured in a substantial helical shape.

Claim 13: The neurostimulation lead of claim 1, further comprising retainer rings mounted about the lead body to retain opposite ends of each of the wire-like elements.

Claim 14: The neurostimulation lead of claim 1, wherein one of the wire-like elements acts as an electrode for neurostimulation current.

Claim 15: The neurostimulation lead of claim 1, wherein the plurality of electrodes include at least four electrodes.

Claim 16: The neurostimulation lead of claim 1, wherein the fixation mechanism is sized to be expandable to a diameter in a range of approximately 2 to 10 mm.

Claim 17: The neurostimulation lead of claim 1, wherein the fixation mechanism is sized to be expandable to a diameter in a range of approximately 4 to 6 mm.

Claim 18: The neurostimulation lead of claim 1, wherein the fixation mechanism is sized to be expandable to a diameter in a range of approximately 6 to 15 mm.

Claim 19: The neurostimulation lead of claim 1, wherein the fixation mechanism is sized to be expandable to a diameter in a range of approximately 9 to 12 mm.

Claim 20: The neurostimulation lead of claim 1, wherein the stimulation lead includes radio-opaque material that is detectable by fluoroscopic imaging.

Claim 21: The neurostimulation lead of claim 1, wherein the lead is one of a sacral lead, a pudendal nerve lead, and a spinal cord stimulation lead.

Claim 22: A neurostimulation system comprising:

an implantable neurostimulation pulse generator;

a lead body having a proximal end and a distal end;

a plurality of stimulation electrodes disposed adjacent the distal end of the lead body;

an electrical conductor to electrically couple the implantable neurostimulation energy generator to a number of the electrodes; and

a fixation mechanism mounted to the lead body at a position between one of the electrodes and the proximal end of the lead body, the fixation mechanism including one or more wire-like elements that are expandable to fix the lead body at a tissue target site, wherein the position is axially displaced from the plurality of stimulation electrodes.

Claim 23: The neurostimulation system of claim 22, wherein each of the wire-like elements includes an elastic material.

Claim 24: The neurostimulation system of claim 22, each of the wire-like elements having a proximal joint where the proximal end of the wire-like element meets the lead body, and a distal

joint where the distal end of the wire-like element meets the lead body, wherein the distal joint is weaker than the proximal joint.

Claim 25: The neurostimulation system of claim 22, wherein each of the wire-like elements includes a shape memory alloy.

Claim 26: The neurostimulation system of claim 22, wherein each of the wire-like elements includes a super-elastic material.

Claim 28: The neurostimulation system of claim 22, further comprising an inner lumen to accommodate a stylet.

Claim 29: The neurostimulation system of claim 22, further comprising a restraint mechanism to restrain the wire-like elements against expansion, wherein the wire-like elements expand upon removal of at least part of the restraint mechanism.

Claim 30: The neurostimulation system of claim 29, wherein the restraint mechanism includes a lead introducer, the lead introducer defining a lead introducer lumen sized to accommodate the stimulation lead body.

Claim 31: The neurostimulation system of claim 29, wherein the restraint mechanism includes a stylet, the stylet accommodated by an inner lumen of the neurostimulation lead.

Claim 32: The neurostimulation system of claim 22, wherein at least a portion of the lead body is elastic, causing a diameter of the lead body portion to decrease when the lead body portion is stretched.

Claim 33: The neurostimulation system of claim 22, wherein each of the wire-like elements is configured in a substantial helical shape.

Claim 34: The neurostimulation system of claim 22, further comprising retainer rings mounted about the lead body to retain opposite ends of each of the wire-like elements.

Claim 35: The neurostimulation system of claim 22, wherein one of the wire-like elements acts as an electrode for neurostimulation current.

Claim 36: The neurostimulation system of claim 22, wherein the electrodes include at least four electrodes.

Claim 37: The neurostimulation lead of claim 22, wherein the fixation mechanism is sized to be expandable to a diameter in a range of approximately 2 to 10 mm.

Claim 38: The neurostimulation lead of claim 22, wherein the fixation mechanism is sized to be expandable to a diameter in a range of approximately 4 to 6 mm.

Claim 39: The neurostimulation lead of claim 22, wherein the fixation mechanism is sized to be expandable to a diameter in a range of approximately 6 to 15 mm.

Claim 40: The neurostimulation lead of claim 22, wherein the fixation mechanism is sized to be expandable to a diameter in a range of approximately 9 to 12 mm.

Claim 41: The neurostimulation system of claim 22, wherein the stimulation lead includes radio-opaque material that is detectable by fluoroscopic imaging.

Claim 42: A method comprising:

inserting a lead introducer into a patient;

inserting a lead into the patient via the introducer, wherein the lead includes a lead body having a proximal end and a distal end, a plurality of stimulation electrodes disposed on the lead

body, and a fixation mechanism mounted to the lead body at a position between one of the electrodes and the proximal end of the lead body, the position being axially displaced from the plurality of stimulation electrodes and the fixation mechanism including one or more wire-like elements that are expandable to fix the lead body at a tissue target site; and

removing a restraint mechanism on the fixation mechanism, thereby permitting the wire-like elements to expand.

Claim 43: The method of claim 42, wherein removing a restraint includes withdrawing at least part of a stylet from a lumen of the lead, thereby releasing the fixation mechanism to expand.

Claim 44: The method of claim 42, wherein removing a restraint includes withdrawing at least a portion of the lead introducer, thereby releasing the fixation mechanism to expand.

Claim 45: The method of claim 42, further comprising:

detaching a distal end of each wire-like element; and

withdrawing the lead from the target site.

Claim 46: The method of claim 42, further comprising:

restraining the expanded fixation mechanism; and

withdrawing the lead from the target site.

Claim 47: The method of claim 42, wherein the restraint mechanism includes a lead introducer, the lead introducer defining a lead introducer lumen sized to accommodate the stimulation lead body.

Claim 48: The method of claim 42, wherein the fixation mechanism is sized to be expandable to a diameter in a range of approximately 2 to 10 mm.

Claim 49: The method of claim 42, wherein the fixation mechanism is sized to be expandable to a diameter in a range of approximately 4 to 6 mm.

Claim 50: The method of claim 42, wherein the fixation mechanism is sized to be expandable to approximately a diameter in a range of approximately 6 to 15 mm.

Claim 51: The method of claim 42, wherein the fixation mechanism is sized to be expandable to approximately a diameter in a range of approximately 9 to 12 mm.

Claim 52: The method of claim 42, wherein each of the wire-like elements includes an elastic material.

Claim 53: A stimulation lead comprising:

a lead body having a proximal end and a distal end;

a plurality of stimulation electrodes disposed on the lead body; and

means for fixing the lead body relative to tissue proximate a tissue target site, wherein the fixing means includes wire-like elements that are expandable to fix the lead body at the tissue target site, wherein the fixing means is mounted to the lead body at a position between one of the electrodes and the proximal end of the lead body, and the position is axially displaced from the plurality of stimulation electrodes.

Claim 54: The lead of claim 53, wherein each of the wire-like elements includes an elastic material.

Claim 55: The lead of claim 53, each of the wire-like elements having a proximal joint where the proximal end of the wire-like element meets the lead body, and a distal joint where the distal end of the wire-like element meets the lead body, wherein the distal joint is weaker than the proximal joint.

Claim 56: The lead of claim 53, wherein each of the wire-like elements includes a shape memory alloy.

Claim 57: The lead of claim 53, wherein each of the wire-like elements includes a super-elastic material.

Claim 58: The lead of claim 53, further comprising means for restraining the wire-like elements against expansion, wherein the wire-like elements expand upon removal of at least part of the restraining means.

Claim 59: The lead of claim 53, wherein the lead is one of a sacral lead, a pudendal nerve lead, and a spinal cord stimulation lead.

Claim 60: The neurostimulation lead of claim 1, further comprising a plurality of retainer rings, wherein the retainer rings mount the wire-like elements to the lead body at proximal ends and distal ends of the wire-like elements

Claim 61: The neurostimulation lead of claim 1, wherein the fixation mechanism is spring-biased.

Claim 62: The neurostimulation system of claim 32, wherein the stylet provides an axial force that stretches the elastic portion of the lead body to restrain the wire-like elements against expansion.

Claim 63: The neurostimulation system of claim 62, wherein the elastic portion of the lead body decreases in length upon removal of the stylet.

EVIDENCE APPENDIX

NONE

RELATED PROCEEDINGS APPENDIX

NONE